IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Continuation Reissue Application of:	)	
	)	Conf. No.: **2112**
Uber, III et al.	)	
	)	Art Unit: **3737**
Serial No. 09/545,582	)	
	)	Examiner: **R. Smith**
Filed: April 7, 2000	)	
	)	
For: Patient Infusion System for Use With MRI	)	

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

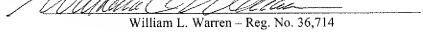
Dear Sir:

Pursuant to 37 C.F.R. § 1.192 and M.P.E.P. § 1205, Applicants appeal the Examiner's final rejection of all pending claims in the referenced application. The fee of $500.00 required under 37 C.F.R. § 41.20(b)(2) is submitted herewith.

I. Real Party in Interest

The real party in interest in this appeal is Medrad, Incorporated, a corporation of the State of Delaware, having a principal place of business at 100 Global View Drive Warrendale, PA 15086.

I hereby certify that this correspondence is being electronically filed with the Commissioner for Patents, Mail Stop Appeal Brief, P.O. Box 1450, Alexandria, VA 22313-1450 on October 1, 2007.



William L. Warren – Reg. No. 36,714

II. Related Appeals and Interferences

There are no appeals or interferences related to the appeal of the present application.

III. Status of Claims

Claims 54-56, 59, 62 and 117-128 are pending and stand finally rejected as set forth in the Office Action mailed December 1, 2006 ("the Final Office Action"). The rejections of claims 54-56, 59, 62 and 117-128 are being appealed.

IV. Status of Amendments

No amendments have been filed subsequent to the Final Office Action.

V. Summary of Claimed Subject Matter

Applicants' invention covers a power injection system for injecting contrast fluid into patients undergoing magnetic resonance imaging ("MRI") procedures. (Col. 2, lines 15-20). The commercial embodiment of Applicants' invention, which was embodied in the first MRI power injection system offered for sale in the U.S., has achieved tremendous success in the marketplace.

The Independent Claims

Independent claim 54 of this application describes an injector used in MRI for injecting a patient with fluid. (Col. 2, lines 15-20). The injector, which is located in a typical MR suite, includes a system controller located outside of the shielded scan room, and an infusion apparatus located inside the shielded room. (Col. 2, lines 52-59; col. 3, lines 40-59). The infusion apparatus includes an injector control unit that is connected to

the system controller by a communication control link, which is substantially non-reactive with the magnetic field of the imaging system while the injector and the MRI system are in operation. (Col. 2, line 56 – col. 3, line 10; col. 3, line 60 – Col. 4, line 1). The claimed arrangement reduces electromagnetic interference and ensures optimum image quality. (Col. 2, lines 45-52).

Independent claim 118 also describes an injector for use with an MRI system. (Col. 2, lines 15-20). The injector in independent claim 118 includes an infusion apparatus and is designed to accommodate two syringes, each of which can be engaged by the injector's own drive mechanism. (Col. 2, lines 52-59; col. 4, lines 17-21). The injector also includes an injector control unit and a system controller that are connected by a communication control link that is substantially non-reactive with the magnetic field of the imaging system while the injector and the MRI system are in operation. (Col. 2, line 56 – col. 3, line 6; col. 3, line 40 – Col. 4, line 1).

Independent claim 124 also describes an MRI injector with a system controller located outside a shielded room and a patient infusion apparatus located inside the shielded scan room. (Col. 2, lines 15-20 and 52-59; col. 3, lines 44-46). The patient infusion apparatus includes infusion apparatus control means and two drive mechanisms, each of which can be engaged by one of the drive mechanisms. (Col. 4, lines 17-21; col. 5, lines 1-10). The injector also includes a substantially non-reactive communication control link. (Col. 2, line 56 – col. 3, line 6; col. 3, line 60 – Col. 4, line 1).

VI. Grounds of Rejection To Be Reviewed On Appeal

The following grounds of rejection are presented for review:

Ground 1

Whether a *prima facie* case of obviousness has been established to support a rejection of claims 54-56 and 59 over Applicants' admission of the prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring."

Ground 2

Whether a *prima facie* case of obviousness has been established to support a rejection of claim 62 over Applicants' admission of the prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" as applied to claim 54 and further in view of the MARK V Injection System Brochure.

Ground 3

Whether a *prima facie* case of obviousness has been established to support a rejection of claim 117 over Applicants' admission of the prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" as applied to Claim 54 and further in view of Boyd.

Ground 4

Whether a *prima facie* case of obviousness has been established to support a rejection of claims 118-119, 121-125, 127, and 128 over Applicants' admission of the prior art in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure.

Ground 5

Whether a *prima facie* case of obviousness has been established to support a rejection of claim 120 over Applicants' admission of the prior art in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure as applied to Claim 118 and further in view of Boyd.

Ground 6

Whether a *prima facie* case of obviousness has been established to support a rejection of claim 126 over Applicants' admission of the prior art in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure as applied to Claim 124 and further in view of Blakeley et al.

VII. Argument

Applicants respectfully submit that each ground of the Examiner's rejection of all the pending claims in the Application should be reversed for the following principal reasons:

A) First, Applicants respectfully submit that the Examiner improperly considered the Applicants' prior work as prior art to the present invention with respect to each of the Examiner's grounds of rejection;

B) Second, the cited prior art does not establish a *prima facie* case of obviousness with regard to each of the Examiner's grounds of rejection relating to claims 54-56, 59, 62 and 117-28; and

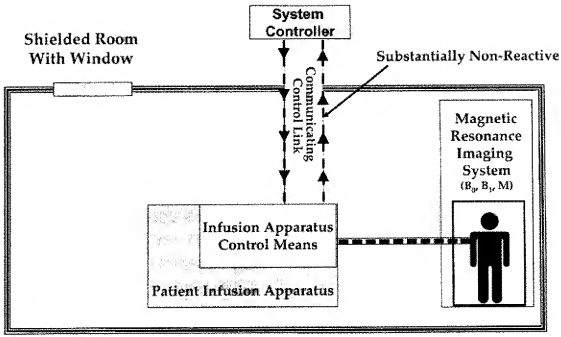
C) Third, for each of the Examiner's grounds of rejection, an analysis of the objective evidence of non-obviousness in the Declarations submitted herewith plainly shows that the invention claimed in the Patent Application is not obvious.

A. Background

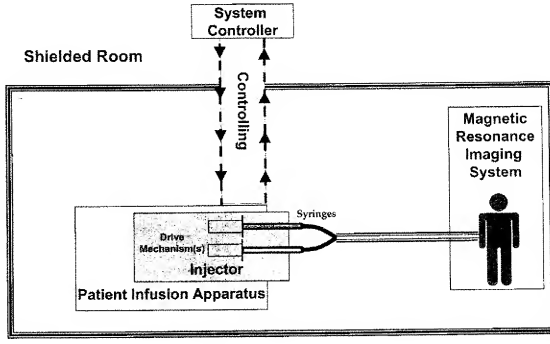
Prior to Applicants' invention, no MRI injectors were available for sale in the United States. In part, this was due to the difficulties of operating such a device in the MRI environment – an environment that involves the use of very high-strength magnetic fields along with extremely sensitive signal detection equipment to obtain diagnostic images of internal anatomy. The high-strength magnetic fields of MRI systems can interfere significantly with the operation of electro-mechanical devices within the electromagnetically shielded scan room. Moreover, operation of electro-mechanical and electronic devices also can interfere with the sensitive MRI scanner and impair an MRI system's ability to obtain usable diagnostic images.

Applicants' invention addresses these problems – the injector described in this Application is designed to prevent substantial interference between the injector and the MRI system. In particular, the control arrangement includes a system controller located outside the shielded scan room and another control component (injector control unit, infusion apparatus control means) located inside the shielded scan room. The communication control link between the system controller and the injector control unit (also infusion apparatus control means) is adapted to be substantially non-reactive with the imaging system. The communication control link of the system is substantially non-reactive when the injector and the MRI system are in operation. Below is a

diagrammatical representation of Applicants' invention, with respect to the elements described above:



The Applicants' invention also addresses another limitation of prior injectors – the inability to engage two syringes of the injector independently with two drive mechanisms. The Applicants' invention includes an infusion apparatus with two drive mechanisms, each adapted to engage one of the two syringes mounted on the injector. This feature allows the injection of two different fluids in rapid succession, which results in several ancillary benefits to the users of the injectors – including improving images and reducing expense. Below is a diagrammatical representation of Applicants' invention, with respect to the elements described immediately above:



B. Applicants' Disclosure of Its Own Work May Not Be Cited as a Prior Art Reference to the Applicant's Invention Claimed in the Application

For each of Examiner's grounds for rejection (Grounds 1-6 listed above in Section VI), Applicants respectfully submit that the Examiner's rejection inappropriately uses the Applicants' own prior work as prior art. For each of the grounds of rejection and every claim now on appeal, the Examiner asserted that certain text appearing in the specification submitted in the present Application (Col. 1, line 22 – Col. 2, line 14) amounted to an "admission of the prior art" by Applicants. In particular, the Examiner cited "Applicant's admission of prior art" as a "reference" disclosing a patient infusion system for use with an MRI system having an infusion apparatus positioned within a shielded room and the system controller located external to the room, wherein the

infusion apparatus includes an injector and a motor to operate the injector. (*See, e.g.*, Final Rejection at p. 2).

The text cited by the Examiner is not an admission or reference to any prior art, but is instead a description of Applicants' own experimental use of prototype devices that were part of the development efforts by Applicants leading to the present invention. (See Declaration of B. Rosen at ¶ 7, 21, originally entered on June 22, 2007, see Evidence Appendix). As such, the Examiner's citation of this material as prior art to the claimed invention was in error.

As a general principle, an inventor's discussion of his own earlier original work cannot be cited as an admission of prior art to show that his later invention is obvious under Section 103. *See Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003) ("One's own work may not be considered prior art in the absence of a statutory basis … ."); *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 223 USPQ 1168 (Fed. Cir. 1984) (the reference described in the "Summary of the Prior Art" was not prior art because it described inventor's own work); *In re Hirayama*, 2007 WL 1877988 (Bd. Pat. App. & Interf. June 29, 2007) (reversing Examiner's rejection based on the use of Applicant's disclosure and impermissible hindsight).

In this case, the text cited by the Examiner is a description of the problems associated with using a patient infusion system in MRI and the Applicants' earlier unsuccessful attempts to overcome these problems. Specifically, the Applicants' discussion of the earlier devices refers to the experimental testing of Applicants' own

prototype injectors, which was performed under the close supervision of the Applicants and was not the work of anyone else.

The extensive development process of the invention, including the lengthy and difficult process of designing and testing the prototype devices, is described in the Declaration of Salvatore Dedola, originally entered on June 22, 2007. (Dedola Decl., ¶¶ 5, 10, see Evidence Appendix). Applicants performed extensive testing and experimentation with prototype devices as part of their efforts to develop an injection system that could operate in the MRI environment. Among the challenges the Applicants' faced was the difficulty of designing an injector that operated as desired but was substantially non-reactive with the MRI system, and used two syringes. (*Id.*). One of the Applicants' experimental prototype devices was tested by Dr. Bruce Rosen in his work at the Massachusetts General Hospital ("MGH"), as part of Applicants' experimentation and development process. (Rosen Dec. at ¶ 7).

In his Declaration, Dr. Rosen confirms that the text cited by the Examiner refers to Applicants' work on its own prototype devices. (Rosen Dec. at ¶ 7 and 21). The text describing the Applicants' work and the challenges they faced was therefore not an admission of prior art, but was rather part of Applicants' inclusive disclosure, as suggested in section 608.01(c)(2) of the Manual of Patent Examine Procedure (MPEP). See also *Riverwood*, 324 F.3d 1356. Applicants should not be penalized for that inclusive disclosure. *Id.*

Moreover, where an applicant submits evidence that a reference discloses the applicant's own work, the reference must not be treated as prior art. *See Riverwood*, 324

F.3d 1356-57 (stating that applicant presented evidence that reference taught applicant's own work); *In re DeBaun*, 687 F.2d 459, 462 (CCPA 1982) (reversing rejection of obviousness based on declaration evidence that reference disclosed applicant's own work); *see also In re Costello*, 717 F.2d 1346, 1348-49 (Fed. Cir. 1983); *Application of Facius*, 408 F.2d 1396, 1402 n.4 (CCPA 1969); *In re Land*, 368 F.2d 866, 879-80 n.11 (CCPA 1966). Any rejection under Section 103 based in part on such a reference must be reversed. *DeBaun*, 687 F.2d at 463.

Thus, an inventor's discussion of his own earlier original work cannot be cited as an admission of prior art to show that his later invention is obvious under Section 103. *See Riverwood Int'l Corp.*, 324 F.3d at 1355. In addition, when the applicant introduces evidence that the reference-in-question merely discloses applicant's own work, the reference must not be considered prior art. *Id.*; *DeBaun*, 687 F.2d at 463.

Applicants therefore submit that the referenced text was erroneously cited by the Examiner as an admission of prior art, and the rejections of claims 54-56, 59, 62, 117-128 are improper and should be reversed.

C. The Cited Prior Art Does Not Establish a *Prima Facie* Case of Obviousness with Regard to the Rejection of Claims 54-56, 59, 62 and 117-128.

Ground 1: Claims 54-56 and 59 over Applicants' Admission of the Prior Art in View of Saini *et al.* and "Patient Anesthesia and Monitoring"

Summary of Examiner's Rejection on Ground 1

The Examiner rejected claims 54-56 and 59, including independent claim 54, as being unpatentable over "Applicant's admission of the prior art" in view of Saini, Sanjay

et al., "*Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media*," Investigative Radiology, vol. 26/No. 8, pp. 748-51 (Aug. 1991) ("Saini *et al.*") and Karlik, S. J. *et al.*, "*Patient Anesthesia and Monitoring at a 1.5-T MRI Installation*," Magnetic Resonance in Medicine 7, pp. 210-221 (1988) ("Patient Anesthesia and Monitoring"). In particular, the Examiner described the "admitted prior art" as teaching a "patient infusion system for use with an MRI system having an infusion apparatus positioned within a shielded room and the system controller located external to the room. The infusion apparatus includes an injector and a motor to operate the injector." (*See* Final Rejection at p. 2). The Examiner described Saini *et al.* as teaching the use of a flexible drive connection between a motor and the injector that it controls. *Id.* The Examiner reasoned that it would been obvious to one skilled in the art to have modified the prior art device such that the connection between the motor and the injector includes a flexible drive connection.

The Examiner further described "Patient Anesthesia and Monitoring" as teaching the use of fiber optic cables in MRI systems to prevent EM (electromagnetic) interference and a window in the shielded room through which a communications link can provide energy. (*Id.* at pp. 9-10). The Examiner further reasoned that it would have been obvious to have further modified the prior art device disclosed by Applicants such that a fiber optic cable is used to provide a communications link between the external controller and the injector unit.

Applicants' Argument Overcoming Rejection on Ground 1

The rejection of claims 54-56 and 59 over Applicants' admission of the prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection.

As discussed above in Section VII.B, Applicants' disclosure of its own work as set forth in the Application is not a prior art reference that can be cited against the invention claimed in the Application, and the Examiner, therefore, improperly cited the Applicants' earlier attempts to solve the problems associated with using a patient infusion system in MRI in its rejection of all the claims pending in this Application. Thus, the referenced discussion should not be cited to reject claims 54-56 and 59.

Moreover, Saini *et al.* and "Patient Anesthesia and Monitoring," with or without Applicants' discussion of its own prior work do not disclose every element of the invention claimed in the Application. "Patient Anesthesia and Monitoring" discloses the configuration of several devices used to monitor and administer anesthesia to patients undergoing MRI examinations. Saini *et al.* discloses an injection system for use in MRI wherein the system controller is within the shielded room and the injector unit only includes a single fluid syringe.

In citing "Patient Anesthesia and Monitoring," the Examiner stated that this reference's use of fiber optic communication links in the MR environment to prevent electromagnetic interference discloses a substantially non-reactive communications link. *See, e.g.*, Examiner's Dec. 1, 2006 Rejection at pp. 2-3. Applicants respectfully submit

that the Examiner's citation to the "Patient Anesthesia and Monitoring" article was improper for three reasons. (Rosen Dec., ¶¶ 26-29).

(1) The article describes systems where some radiofrequency interference is observed, in essence teaching away from the invention claimed in the Application;

(2) The claimed invention requires a *communication control link*, but "Patient Anesthesia and Monitoring" only discloses a "communications link;" and

(3) This article does not teach the arrangement of the claimed invention, in which a substantially non-reactive communication control link connects the system controller outside the shielded room and an injector control unit inside the shielded room. (Rosen Dec. at ¶ 28).

To establish *prima facie* obviousness, the prior art reference (or references when combined) must teach all of the elements of the claimed invention. *KSR*, 127 S.Ct. at 1741; *see also In re Shannon*, 2007 WL 2219583 (Bd. Pat. App. & Interf. Aug. 1, 2007) (reversing examiner's obviousness rejection for failure of prior art to teach all elements of claimed invention). Thus, an Examiner's obviousness rejection that is based on *ex post* reasoning – *i.e.*, impermissible hindsight – cannot be sustained. "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." *KSR*, 127 S.Ct. at 1742.

Here, "Patient Anesthesia and Monitoring" does not disclose a substantially non-reactive link, and, in effect, teaches away from the invention claimed in the Application. (Rosen, ¶ 28). That is, in several instances, "Patient Anesthesia and Monitoring" discloses that the RF shield of the MR suite is breached and RF interference can be

observed. ("Patient Anesthesia and Monitoring" at p. 219 and 220). A prior art reference that teaches away from the claimed invention is a significant factor to be considered in determining obviousness and does not establish a *prima facie* case of obviousness. M.P.E.P. § 2145; M.P.E.P. § 2143; *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); *In re Hedges*, 783 F.2d 1038, 1039 (Fed. Cir. 1986).

Second, "Patient Anesthesia and Monitoring" does not disclose a substantially non-reactive communication control link. Instead, the reference only discloses a "communications link" as opposed to the claimed *communication control link*. This difference is significant, as identified by Dr. Rosen in his Declaration. (Rosen Decl., ¶ 27). Transmission of control information across a communication control link between controlling components presents challenges that are separate and apart from the communication of drive power or monitoring data. (*Id.*). This distinction was made clear by the Patent Office during the prosecution of this Application's parent application that resulted in U.S. Patent No. RE37,602 – in which Applicants were required by the Patent Office to amend claims to include the "*control*" element.

Third, the communication link in "Patient Anesthesia and Monitoring" does not connect a system controller that is outside the shielded room to another control component (the injector control unit) that is inside the shielded room. The systems described in "Patient Anesthesia and Monitoring" do not include distribution of control between two components – one inside and one outside of the RF shielded room – but instead the reference identifies devices with a single control component.

Therefore, Applicants respectfully submit that Examiner's conclusion was erroneous and that it would not have been obvious for a person of ordinary skill in the art in view of "Patient Anesthesia and Monitoring" to include a substantially non-reactive communication control link between a system controller and injection control unit.

In addition, Saini *et al.* does not disclose, teach or suggest a *substantially nonreactive communications control link* as claimed in the present Application. Instead, Saini *et al.* describes and discloses an injection system with motors that do not create interference with the main magnetic field of a magnetic resonance imaging scanner. The strength and shape of the main magnetic field of the scanner, also known as B_0, can be affected by the presence of electromagnetic motors or other ferrous metal objects. This type of interference can result in non-uniform disturbances in the strength of the main magnetic field in certain areas, or "perturbations."

Perturbations of this type affect the images produced by the MRI scanner, principally by causing geometric distortion in the images. Saini *et al.* concerned whether geometric distortions of this type were caused by the motors of the injector that was the subject of the article. In his Declaration, Dr. Rosen noted that Saini *et al.* did not disclose whether the system reacted with the magnetic fields of the imaging system other than the main magnetic field (B_0). It should be noted that Dr. Rosen was a co-author of Saini *et al.*

The claimed *substantially nonreactive communications control link,* however, is directed to a control link that avoids creating a different type of interference with the scanner. As pointed out in the specification of the application, electromagnetic radiation

or "noise" is also a problem for MRI scanners. (Col. 1, line 31 to Col. 2, line 3). As, the specification points out, "One ... problem is the need to provide a communications link between the externally located controller and the contrast media injectors, without introducing extraneous electromagnetic radiation." (Col. 1, lines 41-44). Saini *et al.* does not deal with the question of whether electromagnetic noise was created by a communications control link.

For all the reasons listed, Saini *et al.* and "Patient Anesthesia and Monitoring," either alone or in combination, neither disclosed, taught, or suggested an MRI injection system having a *substantially non-reactive communications control link* extending between a system controller outside the shielded room to an injection control unit inside the shielded room.

Therefore, the Examiner's rejection of claims 54-56 and 59 should be reversed.

Ground 2: Claim 62 over Applicants' admission of the prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" as Applied to Claim 54 and further in view of MARK V Injection System Brochure

Summary of Examiner's Rejection on Ground 2

Dependent claim 62 was rejected by the Examiner as being unpatentable over "Applicant's admission of the prior art" in view of Saini *et al.* and "Patient Anesthesia and Monitoring," as applied to claim 54 above, and further in view of the MARK V injection System Brochure. The Examiner described the MARK V Injection System Brochure, which the Examiner stated is disclosed in Saini *et al.*, as teaching an injection system that includes two syringes and one drive mechanism. The Examiner reasoned that

it would have been obvious to one skilled in the art to have further modified the prior art disclosed by Applicant such that the injection system includes two drive mechanisms, one for each of the syringes. The Examiner further reasoned that such a modification would allow for faster operation of the injector.

Applicants' Argument Overcoming Rejection on Ground 2

The rejection of claim 62 over Applicant's admission of prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" as applied to claim 54 and further in view of the MARK V Injection System Brochure is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection.

As discussed above in Section VII.B, Applicant's disclosure of its own work may not be cited as a prior art reference to Applicant's invention and therefore the referenced discussion should not be used as cited prior art to reject claim 62.

Also, for the reasons discussed above in Section VII.C.Ground 1, the rejection of claims 54-56, and 59 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was erroneous. Thus, the rejection of claim 62 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was also erroneous for the same reasons.

In addition, claim 62 would not have been obvious in view of the MARK V Injection System Brochure because (1) that reference fails to disclose two syringes each engaged with a drive mechanism and (2) the Examiner's conclusion that it would have been obvious to modify the configuration of the injection system in the MARK V Injection System Brochure to include two syringes each engaged by a drive mechanism is

contrary to the disclosure of Saini *et al.*, which expressly teaches away from the invention claimed in the Application.

To establish *prima facie* obviousness, the prior art reference (or references when combined) must teach all of the elements of the claimed invention. *KSR*, 127 S.Ct. at 1741; *In re Shannon*, 2007 WL 2219583 (Bd. Pat. App. & Interf. Aug. 1, 2007) (reversing examiner's obviousness rejection for failure of prior art to teach all elements of claimed invention). In this Application, notably the Examiner acknowledged in the Final Office Action of December 1, 2006 that the MARK V Injection System Brochure does not disclose the use of two syringes and two drive mechanisms. Instead, the Examiner erroneously stated that "[i]t would have been obvious to one skilled in the art to have further modified the prior art disclosed by applicant such that the injection system includes two drive mechanisms, one for each syringes." The Examiner's conclusion, however, is not supported by a reference cited in the Application nor is it supported by any evidence of what one of ordinary skill in the art would have known.

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited in *KSR*, 127 S. Ct. at 1741). Thus, the Examiner only reached this unsupported conclusion using improper *ex post* reasoning – *i.e.*, impermissible hindsight, and the Supreme Court has warned that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." *KSR*, 127 S.Ct. at 1742.

The Applicants respectfully submit that the evidence of record and before the Examiner support the opposite conclusion – that it would not have been obvious to a person of ordinary skill in the art to further modify the prior art to include two drive mechanisms. Dr. Bruce Rosen, a co-author of Saini *et al.*, stated in his Declaration that when he and his fellow co-authors were faced with an injection system with a single syringe, they did not know to modify the injector to include two drive mechanisms, and that they considered a fundamentally different approach from the claimed invention. (*See* Rosen Dec., ¶ 22-25).

Moreover, the disclosure of Saini *et al.* teaches away from the invention claimed in the Application. Saini *et al.* describes an injector with a single syringe. On page 751 (MD123699) of the article, the authors, including Dr. Rosen, state:

> the major impediment for routine clinical use is the absence of a set-up that will allow the contrast agent to be flushed out of the connecting tubing. Such a system is needed to reduce waste of the contrast medium and to prevent its stasis in the arm. A potential solution may be gently to aspirate gadopentetate dimeglumine after saline has been preloaded into the syringe. … Alternatively, specially designed compartments … can be devised that can be placed between the syringe and the connecting tubing.

Thus, instead of suggesting the use of two syringes and two drive mechanisms to allow the injection of contrast solution and saline solution, Saini *et al.* teaches an entirely different solution of loading ("aspirating") a single syringe with separate layers of contrast and saline, or alternatively adding a special compartment. (Saini *et al.* at p. 751 (MD123699)). The claimed invention's feature of two syringes and two drive mechanisms in an MR injector is not taught or suggested in Saini *et al.*

A prior art reference that teaches away from the claimed invention is a significant factor to be considered in determining obviousness and does not establish a *prima facie* case of obviousness. M.P.E.P. § 2145; M.P.E.P. § 2143; *In re Fine*, 837 F.2d at 1074; *In re Hedges*, 783 F.2d at 1039. Here, Saini *et al.*, authored by skilled artisans, is relevant evidence of the knowledge of a person skilled in the art at the time of the invention as is the Declaration of Dr. Rosen, one of the authors of Saini *et al.* Saini *et al.* teaches away from the invention claimed in the Application and therefore a person having ordinary skill in the art would not have been motivated to modify the injection system disclosed in the MARK V Injection System Brochure in the manner claimed in the Application as the Examiner suggests in the Final Office Action.

Thus, no *prima facie* case of obviousness has been established. Claim 62 is non-obvious over Saini *et al.* and "Patient Anesthesia and Monitoring" in view of the MARK V Injection System Brochure.

Ground 3: Claim 117 over Applicants' admission of the prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" as applied to Claim 54 and further in view of Boyd

Summary of Examiner's Rejection on Ground 3

The Examiner rejected dependent claim 117 as being unpatentable over "Applicant's admission of the prior art" in view of Saini *et al.* and "Patient Anesthesia and Monitoring," as applied to claim 54 above, and further in view of Boyd. The Examiner described Boyd as teaching an injector having a battery for powering the injector. The Examiner reasoned that it would have been obvious to one skilled in the art

to have further modified the prior art disclosed by Applicant such that it includes a battery for powering the injector.

Applicants' Argument Overcoming Rejection on Ground 3

The rejection of claim 117 over Applicant's admission of prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" as applied to claim 54 and further in view of Boyd is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection.

As discussed above in Section VII.B, Applicant's disclosure of its own work may not be cited as a prior art reference to Applicant's invention and therefore the referenced discussion should not be used as cited prior art to reject claim 117.

Also, for the reasons discussed above in Section VII.C.Ground 1, the rejection of claims 54-56, and 59 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was erroneous. Thus, the rejection of claim 117 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was also erroneous for the same reasons.

The Examiner also rejected claim 117 further in view of Boyd because Boyd teaches an injector having a battery for powering the injector. Boyd, however, does not disclose an injector for use in MRI with a communication control link extending between a system controller that is located outside the shielded scan room and an injector control unit that is located inside the shielded scan room that is substantially non-reactive with the imaging system. Instead, Boyd discloses an injection apparatus which is positioned, with the exception of the power supply, in contact with the skin during the injection

operation. (Boyd '328 patent, col. 1, line 66 – col. 2, line 41). Boyd does not teach an injector to be used in MRI.

Thus, no *prima facie* case of obviousness has been established. Claim 117 is non-obvious over Saini *et al.* and "Patient Anesthesia and Monitoring" in view of Boyd.

Ground 4: Claims 118-119, 121-125, and 127-28 over Applicant's admission of the prior art in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and MARK V Injection System Brochure

Summary of Examiner's Rejection on Ground 4

The Examiner rejected claims 118-19, 121-25, and 127-28, including independent claims 118 and 124, as being unpatentable over "Applicant's admission of the prior art" in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure. The Examiner described the disclosures of Saini *et al.* and "Patient Anesthesia and Monitoring" in the same manner as described above in the rejection of claims 54-56 and 59 and described the disclosure of the MARK V Injection System Brochure in the same manner as described above in the rejection of claim 62.

Applicants' Argument Overcoming Rejection on Ground 4

The rejection of claims 118-19, 121-25 and 127-28 over Applicant's admission of prior art in view of Saini *et al.* and "Patient Anesthesia and Monitoring" as applied to claim 54 and further in view of MARK V Injection System Brochure is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection.

As discussed above in Section VII.B, Applicant's disclosure of its own work may not be cited as a prior art reference to Applicant's invention and therefore the referenced

discussion should not be used as cited prior art to reject claims 118-19, 121-25 and 127-28.

Also, for the reasons discussed above in Section VII.C.Ground 1, the rejection of claims 54-56, and 59 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was erroneous. Thus, the rejection of claims 118-19, 121-25 and 127-28 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was also erroneous for the same reasons.

Further, for the reasons discussed above in Section VII.C.Ground 2, the rejection of claim 62 further in view of the MARK V Injection System Brochure was erroneous. Thus, the rejection of claims 118-19, 121-25 and 127-28 further in view of the MARK V Injection System Brochure was also erroneous for the same reasons.

Thus, no *prima facie* case of obviousness has been established. Claims 118-19, 121-25 and 127-28 are non-obvious over Saini *et al.* and "Patient Anesthesia and Monitoring" as applied to claim 54 and further in view of MARK V Injection System Brochure.

Ground 5: Claim 120 Over Applicants' Admission of the Prior Art in View of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure as applied to Claim 118 and further in view of Boyd

Summary of Examiner's Rejection on Ground 5

The Examiner rejected dependent claim 120 as being unpatentable over "Applicant's admission of the prior art" in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure as applied to claim 118 above,

and further in view of Boyd. The Examiner described the disclosure of Boyd in the same manner as the rejection of claim 117.

Applicants' Argument Overcoming Rejection on Ground 5

The rejection of claim 120 over Applicant's admission of prior art in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure as applied to claim 118 and further in view of Boyd is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection.

As discussed above in Section VII.B, Applicant's disclosure of its own work may not be cited as a prior art reference to Applicant's invention and therefore the referenced discussion should not be used as cited prior art to reject claim 120.

Also, for the reasons discussed above in Section VII.C.Ground 1, the rejection of claims 54-56, and 59 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was erroneous. Thus, the rejection of claim 120 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was also erroneous for the same reasons.

Further, for the reasons discussed above in Section VII.C.Ground 2, the rejection of claim 62 further in view of the MARK V Injection System Brochure was erroneous. Thus, the rejection of claim 120 further in view of the MARK V Injection System Brochure was also erroneous for the same reasons.

Also, as discussed above in Section VII.C.Ground 3, the rejection of claim 117 further in view of Boyd was erroneous. Thus, the rejection of claim 120 further in view of Boyd was also erroneous for the same reasons.

Thus, no *prima facie* case of obviousness has been established. Claim 120 is non-obvious over Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure in view of Boyd.

Ground 6: Claim 126 over Applicants' admission of the prior art in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure as applied to Claim 124 and further in view of Blakeley et al.

Summary of Examiner's Rejection on Ground 6

The Examiner rejected dependent claim 126 as being unpatentable over "Applicant's admission of the prior art" in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure, as applied to claim 124 above, and further in view of Blakeley *et al.* (U.S. Patent No. 4,694,837). The Examiner described Blakeley as teaching an injector having a communications link – that comprises either an optical fiber arrangement or an infrared link – that is adapted to be substantially non-reactive with the MRI system. The Examiner reasoned that it would have been obvious to one skilled in the art to have further modified the prior art disclosed by Applicant such that the communications link comprises means for transmitting and receiving infrared energy.

Applicants' Argument Overcoming Rejection on Ground 6

The rejection of claim 126 over Applicant's admission of prior art in view of Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure as applied to claim 124 and further in view of Blakeley is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection.

As discussed above in Section VII.B, Applicant's disclosure of its own work may not be cited as a prior art reference to Applicant's invention and therefore the referenced discussion should not be used as cited prior art to reject claim 126.

Also, for the reasons discussed above in Section VII.C.Ground 1, the rejection of claims 54-56, and 59 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was erroneous. Thus, the rejection of claim 126 in view of Saini *et al.* and "Patient Anesthesia and Monitoring" was also erroneous for the same reasons.

Further, for the reasons discussed above in Section VII.C.Ground 2, the rejection of claim 62 further in view of the MARK V Injection System Brochure was erroneous. Thus, the rejection of claim 126 further in view of the MARK V Injection System Brochure was also erroneous for the same reasons.

Moreover, Blakely does not disclose an injector for use in MRI with a communication control link extending between a system controller that is located outside the shielded scan room and an injector control unit that is located inside the shielded scan room that is substantially non-reactive with the imaging system.

Thus, no *prima facie* case of obviousness has been established. Claim 126 is non-obvious over Saini *et al.*, "Patient Anesthesia and Monitoring" and the MARK V Injection System Brochure in view of Blakeley.

D. The Examiner Failed to Give Meaningful Consideration to Applicants' Rule 132 Declarations, Which Contained Evidence of Objective Indicia of Non-Obviousness Rebutting any *Prima Facie* Showing of Obviousness

Applicants respectfully submit that the Examiner committed legal error by not giving meaningful consideration to rebuttal evidence and that the Examiner's rejection should be vacated on this ground alone. Moreover, the evidence of objective indicia of non-obviousness presented by Applicants rebuts any arguable showing of obviousness of the pending claims.

1. The Examiner Committed Legal Error by not giving Meaningful Consideration to the Declarations Submitted by Applicant

When an applicant puts forth evidence rebutting a showing of obviousness in the form of declarations, the Examiner must consider that evidence. *See In re Sullivan*, 2007 WL 2433841, *4 (Fed. Cir. Aug. 29, 2007); *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (stating that "all evidence of nonobviousness must be considered when assessing patentability"); *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983). When present, an Examiner must give declarations containing objective evidence of non-obviousness "meaningful consideration" before arriving at its conclusion. *Sullivan*, 2007 WL at *6. Failure to consider such evidence is grounds for vacating an Examiner's rejection. *Sullivan*, 2007 WL at *4; *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (vacating an examiner's rejection that was affirmed by the Board because the examiner failed to fully consider a factual declaration submitted by applicant).

In *Sullivan*, the Federal Circuit vacated a Board decision that affirmed an Examiner's obviousness rejection because the Board failed to give meaningful consideration to declarations containing competent, objective evidence of non-obviousness. 2007 WL at **4-7. The applicant in that case submitted three declarations – one authored by an expert in the field and two others authored by inventors of the claimed invention. *Id.* at **5-6. The declarations included three material pieces of rebuttal evidence: (1) evidence that the prior art taught away from the claimed invention, (2) evidence of unexpected properties or results from the use of the claimed invention, and (3) evidence that skilled artisans would have expected the claimed invention to fail. *Id.* The Federal Circuit rejected the Director's arguments and vacated the Board's decision for failing to give meaningful consideration to the declarations submitted by the applicant. *Id.* at *7.

Here, the Examiner also gave short shrift to the Rule 132 Declarations that were submitted by Applicants to rebut any arguable showing of obviousness. Applicants note that the Declarations filed pursuant to Section 1.132 have been entered by the Examiner. (*See* June 22, 2007 Advisory Action). In the June 22, 2007 Advisory Action, the Examiner merely stated, in relevant part:

> The declaration (sic) directed to commercial success have been considered but are not sufficient to overcome the prior art rejections. The remaining declarations have been considered but are insufficient to overcome the prior art rejections particularly in view of previous declarations submitted by applicant.

June 22, 2007 Advisory Action at 2.

The Applicants submit that the Examiner's statements suffer from several deficiencies. First, the two sentences recited above provided by the Examiner are far from the "meaningful consideration" that is required by the Federal Circuit before arriving at a patentability determination. *Sullivan*, 2007 WL at *4. Moreover, the Examiner's characterization of the Declarations is not an accurate reflection of the evidence contained within the Declarations. The Applicants submitted multiple Declarations that included evidence of commercial success, including one Declaration from an independent user of the commercial machine that embodies the claimed invention which provides a nexus between commercial success and the claimed invention. *See* Declaration of John Dick, Jr. Further, the Declarations submitted by Applicants, as discussed in more detail below, provide overwhelming evidence of not just commercial success and a nexus, but also evidence of the prior art teaching away from the claimed invention, evidence of copying of the claimed invention, evidence that others failed to design similar products and evidence of the difficulties experienced in developing the invention claimed, among others.

Applicants also note that in the June 22, 2007 Advisory Action the Examiner stated that the Declarations did not place the pending claims in condition of allowance, "particularly in view of previous declarations submitted by applicant." (emphasis added). *See* June 22, 2007 Advisory Action at 2. Applicants have submitted no previous Section 132 declarations in this application. While reissue declarations under Section 1.175 were submitted, Applicants do not believe those declarations addressed any facts or circumstances that could possibly relate to the Examiner's reasons for maintaining the

rejections. As such it appears that the Examiner's reliance on previous declarations may be in error. Applicants invite the Examiner to identify the materials referenced as "previous declarations" in the Advisory Action.

In view of these arguments, Applicants respectfully submit that the Examiner's rejection of the pending claims on appeal was improper for a failure to give meaningful consideration to the Rule 132 Declarations submitted by Applicants and that on this basis alone the Examiner's rejection should be reversed.

2. The Evidence of Objective Indicia of Non-Obviousness Presented by Applicants Rebuts Any *Prima Facie* Showing of Obviousness and Indicates that the Invention Claimed in the Present Application is Not Obvious

Objective indicia of non-obviousness remain important and must be considered, where appropriate, in every obviousness determination. *See Sullivan*, 2007 WL at **4-7; *KSR*, 127 S.Ct. at 1739 (citing *Graham*, 383 U.S. at 17); *see also Strotoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Evaluating obviousness therefore requires a careful evaluation of both the combined teachings of the applied prior art **and** the objective evidence of non-obviousness supplied by Applicants. See *In re Oetiker*, 977 F.2d 1443, 1445-46 (Fed. Cir. 1992).

The Supreme Court in *Graham* stated that objective indicia of non-obviousness, such as commercial success and the failure of others to develop the claimed invention, can be used "to give light to the circumstances surrounding the origin of the subject matter sought to be patented." 383 U.S. at 17-18. The importance of objective indicia of non-obviousness was recently confirmed in *In re Sullivan*, where the Federal Circuit

vacated the Board's decision because it failed to properly considered declarations that included competent objective evidence of non-obviousness. 2007 WL at **4-7.

In some instances, evidence of the so-called secondary considerations can be the most informative on the obviousness question because it eliminates any possibility of impermissible hindsight. *See Stratoflex*, 713 F.2d at 1538. Moreover, as discussed in detail above, failing to properly consider the objective indicia of non-obviousness at all in an obviousness determination is improper. *See Soni*, 54 F.3d at 750-51 (reversing Board's decision to affirm Examiner's rejection based on rebuttal evidence); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 206 (Fed. Cir. 1985); *see also Ex Parte Shiek*, 1999 WL 33205719, *2 (Bd. Pat. App. & Int. Jan. 1, 1999) (reversing examiner's rejection based on applicant's evidence of secondary considerations, which overcame any showing of obviousness).

In *Ex Parte Shiek*, the examiner rejected the pending claims based on obviousness. 1999 WL 33205719, *1 (Bd. Pat. App. & Int. Jan. 1, 1999). On appeal, the Board confirmed that the teachings of the prior art references did establish a *prima facie* showing of obviousness, but reversed the examiner's rejection based on an evaluation of the objective indicia of obviousness. *Id.* at *2. In particular, the applicant in *Shiek* showed evidence, through a Rule 132 declaration, of commercial success, copying by the appellant's competitors, and customer and expert response to the embodiment of the claimed invention. *Id.*

Here, Applicants have submitted overwhelming evidence of objective indicia of non-obviousness, including commercial success, difficulties in developing the claimed

invention, inability of others to develop a working device such as the claimed invention and copying of the invention, as detailed in the four declarations submitted by Applicants pursuant to 37 C.F.R. Section 1.132. Moreover, as discussed in detail above, it does not appear from the June 22, 2007 Advisory Action that the four declarations submitted by Applicants were fully considered by the Examiner. A failure to properly consider objective evidence of non-obviousness can be grounds for a reversal of a rejection. *See Ashland Oil, Inc.*, 776 F.2d at 206.

The attached declarations discuss in detail various objective indicia of non-obviousness, as described below:

1. Declaration of Dr. Bruce Rosen (originally entered on June 22, 2007, see Evidence Appendix)

Dr. Rosen, a co-author of the *Saini et al.* article, is a person of ordinary skill in the art. (Rosen Dec. at ¶¶ 1-5). Dr. Rosen confirms the commercial success of Applicants' products and establishes the nexus between the commercial success and the aspects claimed in the present Application. (Rosen Dec. at ¶¶ 8-13). Dr. Rosen also identifies copying of the claimed invention by a competing company. (Rosen Dec. at ¶¶ 14-18). Dr. Rosen further states that a non-reactive injector system that incorporates two syringes was unknown in the art prior to the invention, and the characteristics of such a system make it commercially desirable. (Rosen Dec. at ¶¶ 22-25). Dr. Rosen also comments on the difficulties of developing an injector that effectively operates in the harsh MR environment. (Rosen Dec. at ¶ 6-7).

Finally, Dr. Rosen analyzes the references cited in the Examiner's rejection. In particular, Dr. Rosen identifies the elements missing from those references and states that there was no knowledge in the art nor a motivation to combine the references in the manner described in the Examiner's rejection. (Rosen Dec. at ¶¶ 26-35). Dr. Rosen concludes that the invention claimed in the Patent Application is not obvious in view of the references cited by the Examiner.

2. Declaration of William Snyder (originally entered on June 22, 2007, see Evidence Appendix)

William Snyder, Applicants' Executive Director of Finance, identifies the overwhelming commercial success of the Applicants' products embodying the invention of the present Application. (Snyder Dec. at ¶¶ 3-7). In particular, Mr. Snyder states that Applicants have experienced over $250 million in sales of the commercial products embodying the claimed invention. (Snyder Dec. at ¶¶ 3-4). Mr. Snyder also confirms that, in the United States, the Applicants enjoy a market share of approximately 85%. (Snyder Dec. at ¶ 7).

3. Declaration of John Dick Jr. (originally entered on June 22, 2007, see Evidence Appendix)

John Dick Jr., an employee of a customer of Applicants that purchased and uses the commercial embodiment of the claimed invention, identifies in his Declaration the benefits of the commercial products. (Dick, Jr. Dec. at ¶ 7-10). Mr. Dick confirms that aspects of the invention that are claimed in the present Application make the products commercially desirable. (Dick, Jr. Dec. at ¶ 6-10). Mr. Dick provides a nexus therefore between commercial success and the claimed invention.

4. Declaration of Salvatore Dedola (originally entered on June 22, 2007, see Evidence Appendix)

Salvatore Dedola, one of the named inventors of the claimed invention and a person having ordinary skill in the art, identifies in his Declaration the difficulties experienced by the Applicants in developing the invention and the skilled attempts to achieve the invention made by the Applicants. (Dedola Dec. at ¶ 5-10). Mr. Dedola also reiterates the commercial success of the products and establishes that any success is a result of the claimed invention. (Dedola Dec. at ¶ 11-13).

The evidence of objective indicia of non-obviousness set forth in these four declarations is objective and overwhelming, and these declarations effectively show that the invention claimed in this Application is non-obviousness. Applicants have provided significant evidence of commercial success in the Rosen, Dedola and Snyder Declarations. Those Declarations confirm that Applicants have enjoyed tremendous success in the market and have been successful in maintaining a strong share of the relevant market. Moreover, Applicants have been able to provide a concrete nexus between the claimed invention and the commercial success through the Dick Declaration. That is, in his Declaration, Mr. Dick states that the non-reactive characteristics of the injector as well as the ability to use two syringes make the commercial embodiment of the claimed invention highly desirable in the marketplace. (Dick, Jr. Dec., ¶¶ 6-10).

Applicants also were able to show evidence of copying. Applicants' primary competitor introduced a device into the market place that incorporates the claimed aspects of Applicants' invention. Moreover, evidence of the amount of time that it took

Applicants' competitors to enter the marketplace with a competing product is evidence that the competitor had difficulty designing a working device. The difficulties faced by Applicants' competitor is similar to the challenges that the Applicants faced during the developmental period of the claimed invention.

Therefore, Applicants believe that the Board should reverse the all of the Examiner's grounds for rejection of all the pending claims on the basis that the objective evidence of non-obviousness provided by Applicants establish that the invention claimed in the Application is not obvious.

In sum, Applicants respectfully submit that Examiner's rejection should be reversed for three primary reasons:

(1) The Examiner improperly characterized Applicants' own work as "prior art;"

(2) No *prima facie* case of obviousness has been established for any of the grounds of rejection; and

(3) Evidence of objective indicia of non-obviousness rebuts any showing of obviousness.

In light of the points raised by Applicants and the Declaration evidence submitted herewith, the cited prior art, as a whole, fails to teach the claimed combination of elements defining Applicants' claimed patient infusion system for use with MRI. No *prima facie* case of obviousness has been established based on the references of record, alone or in combination. The rejections are therefore improper and must be withdrawn.

VIII. Claims Appendix

The appendix containing a copy of the claims involved in the appeal can be found in Appendix I.

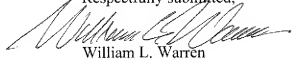
IX. Evidence Appendix

The appendix for evidence can be found in Appendix II.

X. Related Proceedings Appendix

The appendix for related proceedings can be found in Appendix III. There are no appeals or interferences related to the appeal of the present application.

Respectfully submitted,



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APPENDIX I – CLAIMS ON APPEAL

54. A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:

an infusion apparatus positioned within a room shielded from electromagnetic interference and operable to inject fluid into a patient during a magnetic resonance imaging procedure, the infusion apparatus comprising an injector and an injector control unit connected by a non-rigid drive connection, said injector control unit including a drive motor;

a system controller positioned external to the shielded room;

a communication control link between the system controller and the injector control unit, the communication control link adapted to be substantially non-reactive with the magnetic resonance maging system during operation of the patient infusion system and the magnetic resonance imaging system to generate diagnostic images of the patient.

55. The patient infusion system of claim 54 wherein the communication control link comprises a fiber optic line.

56. The patient infusion system of claim 54 wherein the communication control link comprises means for transmitting and receiving electromagnetic energy through a window in the shielded room.

59. The patient infusion system of claim 54 wherein the communication control link transmits electromagnetic energy.

62. The patient infusion system of claim 54, wherein the infusion apparatus further comprises two drive mechanisms and is adapted to accommodate two syringes for injecting fluid into the patient during a magnetic resonance imaging procedure, each syringe being operably engageable with a respective one of the drive mechanisms.

117. The patient infusion system of claim 54, further comprising at least one battery for powering the infusion apparatus without substantial interference with the magnetic resonance imaging system.

118. A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:

an infusion apparatus positioned within a room shielded from electromagnetic interference, the infusion apparatus comprising:

an injector adapted to accommodate two syringes mountable thereon for injecting fluid into a patient during a magnetic resonance imaging procedure;

two drive mechanisms, each drive mechanism comprising a drive motor and being engageable with a respective one of the two syringes; and

an injector control unit positioned within the shielded room;

a system controller positioned external to the shielded room; and

a communication control link between the system controller and the injector control unit, the communication control link adapted to be substantially non-reactive with the magnetic resonance imaging system during operation of the patient infusion system and the magnetic resonance imaging system to generate diagnostic images of the patient.

119. The patient infusion system of claim 118 wherein the drive motors are electric drive motors.

120. The patient infusion system of claim 118 wherein the injector control unit comprises a battery for powering the infusion apparatus.

121. The patient infusion system of claim 118 wherein each of the drive mechanisms includes a non-rigid drive connection.

122. The patient infusion system of claim 118 wherein the communication control link comprises a fiber optic line.

123. The patient infusion system of claim 118 wherein the communication control link comprises means for transmitting and receiving electromagnetic radiation through a window in the shielded room.

124. A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:

a) a room shielded from electromagnetic interference;

b) a system controller external to the shielded room;

c) a patient infusion apparatus within the shielded room and including infusion apparatus control means for controlling an infusion operation;

d) the patient infusion apparatus further including two drive mechanisms each including a drive motor, and an injector adapted to accommodate two syringes mountable thereon for injecting fluid into a patient during a magnetic resonance imaging procedure, each of the syringes operably engageable with a respective one of the drive mechanisms; and,

e) a communication control link between the system controller and the infusion apparatus control means, the control link adapted to be substantially non-reactive with the imaging system.

125. The patient infusion system of claim 124, wherein the communication control link transmits electromagnetic energy.

126. The patient infusion system of claim 124, wherein the communication control link includes means for transmitting and receiving infrared electromagnetic energy.

127. The patient infusion system of claim 124, wherein the communication control link includes means for transmitting and receiving electromagnetic energy in the visual range.

128. The patient infusion system of claim 124, wherein the room shielded from electromagnetic interference includes a viewing window; and wherein the communication control link includes means for transmitting and receiving electromagnetic energy through the viewing window.

APPENDIX II: Evidence Appendix

1. Declaration of Dr. Bruce Rosen: The Declaration of Dr. Bruce Rosen was submitted by the Applicants to the Examiner on May 31, 2007 entitled Response Under 37 C.F.R. § 1.111. The Declaration of Dr. Rosen was entered into the record by the Examiner in an Advisory Action dated June 22, 2007.
2. Declaration of Salvatore Dedola: The Declaration of Salvatore Dedola was submitted by the Applicants to the Examiner on May 31, 2007 entitled Response Under 37 C.F.R. § 1.111. The Declaration of Mr. Dedola was entered into the record by the Examiner in an Advisory Action dated June 22, 2007.
3. Declaration of William Snyder: The Declaration of William Snyder was submitted by the Applicants to the Examiner on May 31, 2007 entitled Response Under 37 C.F.R. § 1.111. The Declaration of Mr. Snyder was entered into the record by the Examiner in an Advisory Action dated June 22, 2007.
4. Declaration of John Dick Jr.: The Declaration of John Dick Jr. was submitted by the Applicants to the Examiner on May 31, 2007 entitled Response Under 37 C.F.R. § 1.111. The Declaration of Mr. Dick was entered into the record by the Examiner in an Advisory Action dated June 22, 2007.

PATENTS
CUSTOMER NO. 29052
ATTY. DOCKET NO. 23578-0010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue Application of:	)	
	)	
Uber, III et al.	)	Art Unit: 3737
Serial No. 09/545,582	)	Examiner: R. Smith
Filed: April 7, 2000	)	
	)	
For: Patient Infusion System for Use With MRI	)	

DECLARATION OF DR. BRUCE ROSEN PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

I, Dr. Bruce Rosen, hereby declare that:

I. INTRODUCTION

1. I am currently the Director of the Massachusetts General Hospital ("MGH") Nuclear Magnetic Resonance Center, and a Professor of Radiology at the Harvard Medical School. I have worked in the field of magnetic resonance imaging (MRI) for over 20 years, have published over 219 articles in the field along with 39 book chapters, and I have been awarded the Gold Medal for my work in the field of Functional Magnetic Resonance Imaging by the International Society of Magnetic Resonance in Medicine.

2. I received my undergraduate degree in Astronomy and Astrophysics at Harvard University in 1977, my master's degree in physics at Massachusetts Institute of Technology

("MIT") in 1980, my medical degree at Hahnemann Medical College in Philadelphia, PA in 1982 and my Ph.D. in Medical Physics at MIT in 1984.

3. I have knowledge of and experience with medical devices relating to magnetic resonance imaging based on my education, experience as a professor of radiology, teaching and performing research in the areas of biomedical and clinical physics and magnetic resonance imaging, and as a clinical and research fellow in the Radiology department at MGH. My work has included the designing of a magnetic resonance imaging spectrometer and working on design teams to determine specifications for electrical equipment used as part of magnetic resonance imaging experiments. I have previously worked as an expert in patent cases involving magnetic resonance imaging technology, including but not limited to *Medrad, Inc. v. Tyco Healthcare Group LP et al.*, Civil Action No. 01-1997 (GLL) (W.D. Pa.), which involved allegations surrounding United States Patent No. RE37,602, a patent that is related to the current Patent Application.

4. I am familiar with the design, development, operation, effectiveness and other characteristics of the patient infusion system which forms the basis of U.S. Pat. App. No. 09/545,582, entitled "Patient Infusion System for Use with MRI," hereinafter referred to as the Patent Application.

5. Based on my education and work experience, at the time of the invention claimed in the Patent Application, I was, and still am, a person having ordinary skill in the art of radiology and related aspects, such as designing devices to effectively operate in the MRI environment.

II. CHALLENGES IN DESIGNING AN INJECTOR IN THE MR ENVIRONMENT

6. Designing an injection system that can operate successfully in an MRI environment is challenging. An injector for MRI must not emit electromagnetic interference or "noise" that would disrupt the highly sensitive magnetic field of the MRI scanner and cause flaws in the images produced by the MRI scanner. Further, an MRI injector must be designed in a way to ensure that the MRI scanner would not detrimentally affect or degrade the operational performance of the injector.

7. While at MGH, I assisted Medrad with testing prototype injector devices to be used with MR imaging systems (prototypes created during development of the invention in the Patent Application). I personally used one of the prototype devices and noted that, at that time, the device did not work effectively in the MRI environment. In particular, the device interfered with the acquisition of images by the MRI system. The prototype device was different than the design and operation of the Spectris injector that MGH currently uses.

III. COMMERCIAL SUCCESS

8. Medrad's Spectris injector was, to my knowledge, the first injector sold in the United States that could successfully operate in an MRI suite. I understand that the Spectris injector embodies the pending claims of the Patent Application. While working at MGH, I have used the Spectris injector to inject patients with contrast medium in conjunction with MRI procedures. The Spectris injector has worked and continues to work effectively to deliver contrast medium to patients in specifically programmed quantities during MRI procedures.

9. The Spectris injector has several components:

a. Two components reside in the control room, which is outside of the shielded scan room. These components include the input device where an operator would program the injector.

b. Two other components reside in the shielded scan room. These components include the motors to drive the syringes and the injector head, which holds two fluid syringes from which fluid is to be injected.

c. The components in the control room are connected to the components inside the shielded scan room via a communication link. A part of the communication link includes two infrared transceivers that communicate through the shielded window.

10. The use of Medrad's Spectris injector during MRI procedures does not create spurious electromagnetic interference that adversely affects the images obtained while the injector is being used. The images obtained by the MRI system while the Spectris injector is in operation do not include artifacts that typically result from such interference. Medrad's Spectris injector assists our facility in making MR images that are diagnostically beneficial.

11. Also, when in use, the strong magnetic fields of the MRI imaging system do not adversely affect the operation of the Spectris injector. That is, the motors and other electronic components of Medrad's Spectris injector operate effectively while the MRI system is acquiring images.

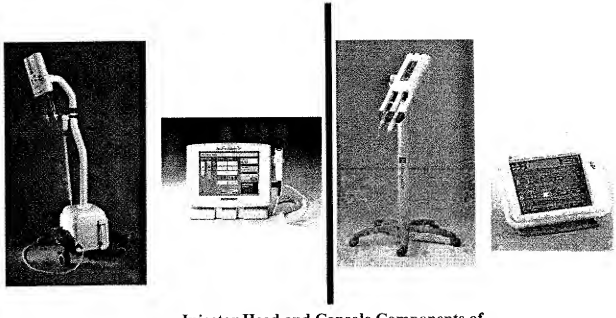
12. Medrad's Spectris injector, therefore, is commercially desirable because it operates effectively in an MRI suite – a harsh environment for electronic devices – without adversely affecting the sensitive MR imaging system and without being adversely affected by the strong magnetic fields of the imaging system.

13. I understand that evidence of secondary considerations, such as commercial success of the product that embodies the claimed invention, is one of the four inquiries for determining if an invention is obvious. The high level of commercial success of Medrad's Spectris and, and the successor to the Spectris, the Spectris Solaris injector, is evidence that the invention claimed in the Patent Application is not obvious.

IV. COPYING OF CLAIMED INVENTION BY APPLICANTS' COMPETITOR

14. I also understand that Applicant's competitor Tyco Healthcare Group LP ("Tyco Healthcare") has sold in the United States an MR injector that copies the features of the claimed invention.

15. Figure 1 (below) is a side-by-side comparison of key components (injector head and console components) of Applicants' commercial embodiment of the invention of the Patent Application (on the left) and the corresponding and equivalent components of Tyco Healthcare's competing product (on the right), the Optistar injector.



Injector Head and Console Components of Applicants' Spectris Solaris Injection System and Tyco Healthcare's Optistar Injector

Figure 1

16. Tyco Healthcare's Optistar injector, on the right in Figure 1 above, is comprised of components that have the same features and functions as the invention claimed in the Patent Application. The Console of Tyco Healthcare's Optistar injector, which is located outside the shielded MR room, controls and regulates the entire injection system. The Console is connected to a component inside the shielded room called the Power Control (not shown in Figure 1) by a substantially non-reactive communication control link, which transmits control information to and from the shielded room without interfering with the MR system. The Power Control component receives control information from the Console and drives the syringes that are located in the injector head component (the component on the left in Figure 1).

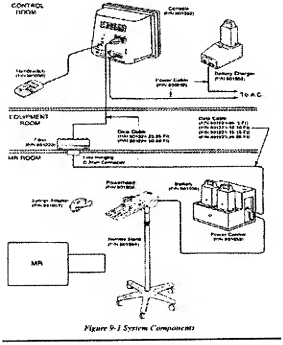


Figure 9-1 System Components

Schematic Diagram of Optistar Injector Showing Location of Components

Figure 2

17. Figure 2 (above) is a diagram from the Service Manual of Tyco Healthcare's Optistar injector showing the physical layout and location of the components of the Optistar. The diagram shows the "Console" (*system controller*) in the Control Room, which is outside of the shielded scan room. The diagram also shows the "Power Control" component (*infusion apparatus control means*) or (*injector control unit*) inside the shielded scan room along with the "Powerhead" component (*injector*). The diagram further shows the data cables (*communication control link*) connecting the Console to the Power Control. It can be seen that the components of the Optistar injector have the same system architecture as the claimed invention and are positioned in the same locations as the components of the claimed invention.

18. I understand that evidence of copying the product that embodies the claimed invention is part of the secondary considerations of non-obviousness. The evidence of copying of Medrad's Spectris injector by Tyco Healthcare is evidence that the invention claimed in the Patent Application is not obvious.

V. THE CLAIMED INVENTION WAS NOT OBVIOUS

19. It is my understanding that the pending Claims of the Patent Application have been rejected under 35 U.S.C. § 103(a) as being unpatentable over a combination of alleged prior art references.

20. I am very familiar with the patient infusion system for use with MRI in the Patent Application. I have reviewed the Examiner's December 1, 2006 rejection and the prior art cited by the Examiner in that rejection. I respectfully submit that the examiner's rejection of the pending claims of the Patent Application based on those references was improper because the invention claimed in the Patent Application would not have been obvious to a person having ordinary skill in the art. I have provided a more detailed response below.

A. "Applicant's Admission of the Prior Art"

21. I understand that the Examiner rejected all of the pending Claims of the Patent Application in view of the "Applicant's admission of the prior art." *See* Dec. 1, 2006 Office Action. It is my understanding that the Examiner cited Medrad's own work on its prototype devices as the admission of prior art, and it is further my understanding, that an Applicant's own work cannot be used as prior art against the Patent Application.

B. The Two Drive Mechanisms Feature of the Claimed Invention Was Not Obvious

22. I understand that the Examiner rejected Claims 62 and 118-128, which require two syringes and two drive mechanisms, in view of a combination of references including (1) the *Saini et al.*, Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media, Investigative Radiology, Vol. 26/ No. 8, Aug. 1991, MD123695-99 (the *Saini et al.* article) and (2) the Mark V Injection System materials. The Examiner noted that the combination of those references failed to disclose two syringes and two drive mechanisms but that a person of ordinary skill in the art would have known to modify the injector disclosed in those references to include two drive mechanisms. I respectfully submit that the Examiner's rejection was improper.

23. I, along with my fellow co-authors of *Saini et al.*, recognized the problem of having a single drive mechanism in the text of the article and proposed solutions for overcoming the problem. (*Id.* at 751(MD123699)). These solutions however were not closely related to the invention claimed in the Patent Application, and they in fact teach away from the two drive mechanisms that are part of the present invention. (*Id.*).

24. The first solution identified by us was to aspirate contrast solution into a syringe that was already preloaded with saline solution – essentially layering contrast solution and saline solution in a single syringe. (*Id.*). The second solution included incorporating different compartments in a single syringe. (*Id.*). The two syringes and two drive mechanisms of the claimed invention do not read on these solutions and these solutions teach away from the claimed invention.

25. I respectfully submit that the Examiner therefore improperly concluded that it would have been obvious to a person skilled in the art to incorporate a second drive mechanism to engage the second syringe based on the *Saini et al.* article and the Mark V injector materials. I was a person of ordinary skill in the art who used the Mark V injection system and it was not obvious to me, or my co-authors, at the time of the invention to incorporate two drive mechanisms to engage two syringes. As a result, pending Claims 62 and 118-128 are allowable and the Examiner's rejection of those claims should be withdrawn.

C. The Substantially Non-Reactive Communication Control Link Feature Was Not Obvious

26. I also understand that the Examiner rejected all of the pending Claims under Section 103 in view of the *Kalik et al.,Patient Ane sthesia & Monitoring at a 1.5-T MRI Installation*, Magnetic Resonance in Medicine 7, pp. 210-221, MAL-PIT-022891-901 (the *Patient Anesthesia & Monitoring* article) in combination with other references. The Examiner cited this reference's use of fiber optic communication links in the MR environment to prevent EM interference as showing a "communications link between the external controller and the injector unit" that has the advantage of preventing "EM interference from affecting the system operation." *See, e.g.,* Examiner's Dec. 1, 2006 Rejection at pp. 2-3. I respectfully submit that

the Examiner's application of the *Patient Anesthesia and Monitoring* reference is improper for two principal reasons.

27. First , the Examiner's application of this reference was improper because the claimed invention requires a *communication control link*, and as the Examiner stated in the rejection, the *Patient Anesthesia and Monitoring* article only shows a "communications link." The link described in the *Patient Anesthesia & Monitoring* article does not transmit control information as required by all of the pending Claims of the Patent Application. Nor does the link disclosed in the *Patient Anesthesia & Monitoring* article connect a control component located outside the shielded room with a control component inside the shielded room – another requirement of all the pending claims.

28. Second, the article teaches away from the invention claimed in the Patent Application because it describes systems with an architecture where the integrity of the shielded perimeter is breached and some RF interference is observed. (*See Patient Anesthesia & Monitoring*, at 219). This teaches away from the invention of the Patent Application. (*Id.*).

29. Therefore, the *Patient Anesthesia & Monitoring* article does not disclose a *communication control link* that is *substantially non-reactive* with the magnetic resonance imaging system. As a result, this claim limitation is not disclosed in the prior art, all of the pending claims are allowable and the rejection of the pending claims on this basis should be withdrawn by the Examiner.

D. A Person Having Ordinary Skill in the Art Would Not Have Been Motivated to Combine the References Cited by the Examiner

30. At the time of the invention claimed in the Patent Application, I and others in the field recognized the need for an injector that was capable of working in the MRI environment.

Medrad's solution, embodied in the Spectris injector and claimed in the Patent Application, did not occur to me or my colleagues at the time of Medrad's invention.

31. Medrad's Spectris injector was the first commercially used injector in the MR environment. The mere fact that no other prior art devices were available to provide contrast media to patients during MRI procedures demonstrates that the Examiner's combination would not have occurred in the ordinary course.

32. At the time of the invention, a person of ordinary skill in the art would not have been motivated to combine the references cited above because they teach away from distributing the control aspects of the system between components inside and outside. The *Saini et al.* article teaches a single control component located inside the shielded room, the Mark V injector has all of the control in the components outside the shielded room and *Patient Anesthesia & Monitoring* teaches either having all the control either inside or outside, but not distributed between components at both locations. Therefore, these references teach away from their combination.

33. Further, these references identified RF interference as a concern, however they did not provide an adequate solution to the problem nor did they provide the solution claimed in the Patent Application. The *Saini* article did not disclose whether the system was reactive with the magnetic fields of the imaging system other than the static field (B_o). Similarly, the *Patient Anesthesia & Monitoring* article noted that the systems disclosed therein created RF interference and did not provide a solution for the problem. The Mark V injector was designed for the angiographic or CT environment and therefore did not address this issue. Therefore, a person having ordinary skill in the art would not have known or been motivated to combine these references.

PATENTS
CUSTOMER NO. 29052
ATTY. DOCKET NO. 23578-0010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue Application of:	)	
	)	
Uber, III et al.	)	
	)	Art Unit: 3737
Serial No. 09/545,582	)	
	)	Examiner: R. Smith
Filed: April 7, 2000	)	
	)	
For: Patient Infusion System for Use With MRI	)	
	)	

DECLARATION OF SALVATORE J. DEDOLA PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

I, Salvatore J. Dedola, hereby declare that:

1. I am a resident of New Kensington, Pennsylvania and have been working as a mechanical design engineer or a supervisor for a mechanical design and manufacturing engineering groups for over 25 years. In 1980, I received my Bachelor of Science degree in Mechanical Engineering from the University of Pittsburgh. I also received a Master of Business Administration degree from the University of Pittsburgh in 1998.

2. I am currently the manager of the Sterile Disposables Manufacturing engineering department at Medrad, Incorporated ("Medrad"). I began working as a mechanical design engineer for Medrad in 1987. Since then I have held the positions of senior mechanical engineer, project engineer, senior project engineer, Mechanical Design Engineering Manager and Program Manager as well as my current position.

3. Prior to working at Medrad, I was a mechanical design engineer for ALCOA where I designed in-plant equipment, a mechanical design engineer for Molytek where I designed manufacturing fixtures and a mechanical design engineer for Vamco where I designed high speed press feeds.

4. I am a named inventor of U.S. Pat. App. No. 09/545,582, entitled "Patient Infusion System for Use with MRI," hereinafter referred to as the Patent Application.

5. Based on my technical education as well as my many years of technical experience in the field, I was at the time of the invention in the Patent Application and I still am a person of ordinary skill in the art of designing and developing patient infusion systems used with MR imaging procedures. In particular, I am familiar with the development of the patient infusion system which forms the basis of the Patent Application. I helped design and develop the system encompassed by the Patent Application, I assisted with the lengthy and difficult process of designing and testing prototype devices and I am familiar with the delay by other manufacturers in developing a competitive product.

6. The challenging design and development process and the difficulties experienced by other manufacturers in developing a competitive product are briefly described below.

The Development Process and Design Challenges

7. When I began my employment at Medrad, I worked on the design for a patient infusion system for use with MRI that resulted in the invention claimed in the Patent Application. I was responsible for, among other things, the non-magnetic injector head of the infusion system. My work included the designing an injector head that would not create extraneous electromagnetic interference with the MRI scanner and would not be adversely affected by the high strength of the high magnetic field of the imaging system. I was also involved in other design aspects.

8. The design of the infusion system took several years to complete. During the design, many obstacles were encountered. It was difficult to design a power injector - an electro-mechanical device - that could operate effectively in a hostile environment such as the MR imaging suite. The MR environment presented at least two challenges. The first challenge was to ensure that the operation of the device would not create spurious electromagnetic interference (EMI) that would significantly reduce the diagnostic capabilities of the MRI system. EMI can cause "artifacts" that mar and distort MR images, impairing the ability of physicians to use the images for diagnostic purposes. The second challenge was to design a device that would not be adversely affected by the strong magnetic fields emitted by the MR imaging system – *i.e.* so that the injector would still operate effectively during the operation of the MRI. These challenges required design solutions such as distributing the control aspects of the injection system between

components that resided inside the shielded room and inside the control room (outside the shielded room), configuring the system so that control signals were transmitted across the communication link that spanned the shielded wall, and using communication transmission techniques that would not interfere with, or be interfered by, the MRI system.

9. Another design concept that was new to this invention and difficult to implement was the use of two syringes that could be simultaneously engaged by drive mechanisms of the injector. By having two syringes engaged in this manner, it was possible to operate the injector to smoothly transition from injecting contrast fluid from one syringe into the patient, to injecting saline solution from the other syringe (or vice versa).

10. Part of the development process for the invention claimed in the Patent Application included designing prototypes and testing those prototypes in the field. The experimentation process spanned at least three different iterations of prototypes and took many years to complete. The feedback from this process allowed us to improve and refine the device and arrive at the design disclosed in the Patent Application.

Commercial Success of Products Embodying the Claimed Invention

11. Medrad sold its first MR power injector, the Spectris, in March 1996 following approval by the U.S. Food and Drug Administration ("FDA") in September 1995. The Spectris consisted of a display control console, master control unit and battery charging unit that were used in the control room of the MR suite; an injector head stand, and head control unit that were used in the scan room; and an optical transmitter receiver pair that provided communications between the modules in the two rooms. Since the Spectris was introduced into the market, it has

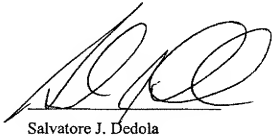
experienced a high level of commercial success, attributable to the invention embodied by the Patent Application.

12. The Spectris embodies the patient infusion system for use with MRI that is disclosed in the Patent Application, and that system has proven to work effectively in conjunction with MRI imaging procedures. The overwhelming commercial success of the Spectris is attributable to the invention disclosed and claimed in the Patent Application.

13. Medrad developed a new MR injector called the Spectris Solaris injector and introduced it in 2002. The Spectris Solaris injector also embodies the claimed invention in the Patent Application. The Spectris Solaris has experienced a high level of commercial success as well.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: May 24, 2007



Salvatore J. Dedola
Medrad, Inc. USA
One Medrad Drive
Indianola, PA 15051

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue Application of:	)	
Uber, III et al.	)	Art Unit: 3737
Serial No. 09/545,582	)	Examiner: R. Smith
Filed: April 7, 2000	)	
For: Patient Infusion System for Use With MRI	)	

DECLARATION OF WILLIAM SNYDER PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

I, William Snyder, hereby declare that:

1. I am currently the Executive Director of Finance at Medrad, Incorporated ("Medrad"). I began working at Medrad in 1997 as Accounting Manager. Since then I have held the positions of Director of Accounting, Director of Finance for the Global Field Organization, regional sales representative, as well as my current position.

2. I am familiar with the commercial sales success of the products that form the basis of the Patent Application. My responsibilities as Executive Director of Finance include

recording, reviewing, and understanding financial indicators for all of Medrad's product lines as well as understanding the competitive marketplace. As a result, I know that Medrad's Spectris and Spectris Solaris injectors have experienced a high level of commercial success and that the Spectris was the only MR injector on the US market from 1996 – 2000.

Commercial Success of Products Embodying the Claimed Invention

3. Medrad sold its first MR power injector, the Spectris, in March 1996 following approval by the U.S. Food and Drug Administration ("FDA") in September 1995. Since the Spectris was introduced into the market, it has experienced a high level of commercial success, attributable to the invention embodied by the Patent Application. The Spectris and its successor, the Spectris Solaris injector, have together enjoyed a high level of commercial success and have reached over $ 250 million in sales worldwide.[1]

4. A summary table showing the total historical sales of Medrad's Spectris and Solaris injectors is represented below:

Region	Products	Sales Revenue (US$)
USA	Spectris & Solaris Injectors	greater than $ 160,000,000
Rest of World	Spectris & Solaris Injectors	greater than $ 90,000,000
Total Worldwide Sales		greater than **$ 250,000,000**

5. The Spectris injector was the only MR power injector sold in the United States from the time it was introduced in 1996 to 2000, for four years. In 2000 Mallinckrodt/Tyco Healthcare introduced a competing product, the Optistar injector. I understand that Medrad has

[1] A current list price for Medrad's Spectris Solaris injection system is $46,000 per injector. *See* 2007 GE Healthcare Diagnostic Imaging Accessories Catalog (catalog can be downloaded at http://apps.gehealthcare.com/apps2/accessories/catalog.jhtml).

accused the Optistar injector of infringing Medrad's U.S. Patent No. Re 37,602 in a case pending in the United States District Court for the Western District of Pennsylvania (Medrad v. Tyco Healthcare, et al., Civil Action No. 01-1997).[2] The Optistar, like the Spectris, is a dual syringe injector in which both syringes are engaged with a drive mechanism, has a system controller outside the shielded room, and uses a communication control link that does not cause interference with MRI imaging procedures.

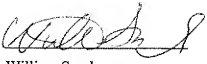
6. Medrad developed a new MR injector called the Spectris Solaris injector and introduced it in 2002. The Spectris Solaris injector also embodies the claimed invention in the Patent Application. The Spectris Solaris has experienced a high level of commercial success as well.

7. Since Medrad began selling the Spectris in March, 1996, Medrad's Spectris and Spectris Solaris injectors have been an overwhelming success. Medrad's U.S. sales of its MR power injectors have increased approximately 600% from 1996 to 2006. Since the introduction of the Spectris, sales of the Spectris and Spectris Solaris have generated a combined worldwide revenue of over $250 million. (*See* Table at Paragraph 4). Through the first quarter of 2007, Medrad has sold over $160 million in the U.S. and over $90 million in the rest of the world. (*Id.*). Based on current market estimates, Medrad has, in the United States, approximately 85% market share of the installed base of MRI power injectors and in 2006, approximately 85% of MRI contrast injectors purchased were bought from Medrad.

[2] I understand that an appeal from this case has made its way through the United States Court of Appeal for the Federal Circuit, with Medrad prevailing. *Medrad, Inc. v. Tyco Healthcare Group LP et al.*, 466 F.3d 1047 (Fed. Cir. 2007). I also understand that Tyco Healthcare is currently seeking a writ of certiorari from the United States Supreme Court.

8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 30, 2007



William Snyder
MEDRAD, INC. USA
100 Global View Drive
Warrendale, PA 15086
USA

34. Therefore, the pending Claims are allowable and the Examiner's rejection of the pending Claims on the basis of the combination of *Saini et al.*,*Patient A nesthesia and Monitoring* and the Mark V materials should be withdrawn.

D. The References Cited by the Examiner, Even if Combined the References Cited by the Examiner

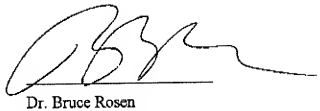
35. As identified in Paragraph 30 above, the combination of *Saini et al.*,*Patient Anesthesia and Monitoring* and the Mark V materials does not disclose two control components, one inside and one outside the shielded room, connected by a substantially non-reactive communication control link. I respectfully submit therefore that the Examiner's rejection was improper for this reason as well and that the Examiner's rejection of the pending claims based on this combination of references should be withdrawn.

VI. GENERAL INFORMATION

36. As noted above, I have worked as an expert in *Medrad, Inc. v. Tyco Healthcare Group LP et al.*, Civil Action No. 01-1997 (GLL) (W.D. Pa.). In that case I was hired and paid by Medrad to testify on a variety of issues, including infringement and validity of United States Patent RE37,602, which is related to the invention claimed in the Patent Application at issue here. Also, upon occasion, Medrad provides MGH with devices for evaluation purposes. I am not, however, being paid or otherwise compensated for providing this declaration.

37. I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 30, 2007



Dr. Bruce Rosen
Professor in Radiology at Harvard Medical School
Director, Athinoula A. Martinos Center for Biomedical Imaging
Department of Radiology, MGH
149 Thirteenth Street, Rm 2301
Charlestown, MA 02129

PATENTS
CUSTOMER NO. 29052
ATTY. DOCKET NO. 23578-0010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue Application of:	)	
	)	
Uber, III et al.	)	
	)	Art Unit: 3737
Serial No. 09/545,582	)	
	)	Examiner: R. Smith
Filed: April 7, 2000	)	
	)	
For: Patient Infusion System for Use With MRI	)	

DECLARATION OF JOHN E. DICK JR. PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, John E Dick Jr., hereby declare that:

1. I am a Registered Radiographic Technologist with advanced certification in Magnetic Resonance Imaging (MR).

2. I am currently the full time lead Magnetic Resonance Imaging ("MRI") technologist and purchasing agent for West Mifflin Imaging. I am also an adjunct MRI/CT Physics instructor at the Community College for Allegheny County and lecturer on the subject.

3. I have 15 years of experience in the field of radiology, with 13 of those years in MRI and 2 in computed tomography.

4. While working at West Mifflin Imaging, I have arranged for the purchase of a Medrad Spectris Solaris injector and used the Spectris Solaris injector to inject patients with contrast medium in conjunction with MRI procedures.

5. My facility uses the Medrad Spectris Solaris injector to inject patients undergoing an MRI procedure with contrast media. The Spectris Solaris injector worked effectively to deliver contrast medium to patients in specifically programmed quantities during MRI procedures.

6. The Spectris Solaris was made up of several components:

a. Two components resided in the control room, which was outside of the shielded scan room. These components included the input device where an operator would program the injector.

b. Two other components resided in the shielded scan room. These components included the motors to drive the syringes and the injector head, which held two fluid syringes from which fluid could be injected.

c. The components in the control room were connected to the components inside the shielded scan room via a fiber optic cable through the MRI RF enclosure by a waveguide.

7. The use of Medrad's Spectris Solaris injector during MRI procedures did not create spurious electromagnetic interference that adversely affected the images obtained while the injector was being used. The images obtained by the MRI system while the Spectris Solaris injector was in operation did not include artifacts that typically result from such interference. Medrad's Spectris Solaris injector assisted our facility in making MR images that were diagnostically beneficial.

8. Also, when in use, the strong magnetic fields of the MRI imaging system did not adversely affect the operation of the Spectris Solaris injector. That is, the motors and other electronic components of Medrad's Spectris Solaris injector operated effectively while the MRI system was acquiring images.

9. To my knowledge, Medrad's Spectris Solaris injector was the first injector sold in the United States that could successfully operate in an MRI suite.

10. Medrad's Spectris Solaris injector, therefore, was commercially desirable because it operated effectively in an MRI suite – a harsh environment for electronic devices – without adversely affecting the sensitive MR imaging system and without being

adversely affected by the strong magnetic fields.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: May 21, 2007

John E Dick Jr

John E. Dick Jr. RT (R,MR)

APPENDIX III: Related Proceedings Appendix

None.